

U.S. Patent Application Serial No. 09/594,577  
Amendment dated October 2, 2003  
Reply to OA of July 2, 2003

### REMARKS

Claims 31-35 and 37-44 are pending in this application. Claim 36 has been canceled herein without prejudice or disclaimer. Amendments to claims 31-33 and 37-44 are proposed herein.

In the final Office action, the Examiner indicates that claims 31-44 are pending. In the amendment of August 12, 2003, adding these claims, claim 36 was unintentionally omitted. Since the Examiner's listing of claims 31-44 as pending indicates that the claims have not been renumbered, Applicants here cancel claim 36 so that there is no confusion as to claim numbering.

In the amendments to claims 37-44, "Anti-S-Le<sup>y</sup>" has been amended to – Anti-Le<sup>y</sup> –. This represents a correction of an error in these claims. These amendments are supported by Table 1 of the present specification on page 27, in which results for Anti-Le<sup>y</sup> antibody (not Anti-S-Le<sup>y</sup>) are presented in the last column.

In claims 38-44, "step (iv)" has been amended to – step (iii) –. This represents a correction of the wording of the claims for clarity. Each of these claims depends from claim 37 and in turn from claim 33, in which step (iii), not step (iv), includes the determination of the presence of a particular cancer based on whether complexes are detected in steps (i)(b), (ii)(b), (iii)(b) and (iv)(b), which involved the first through fourth proteins.

Amendments have also been made for clarity in response to the rejections under 35 U.S.C. 112, as discussed below.

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**Claims 31-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The Examiner refers to the recitation of "protein being one that selectively binds to a first sugar chain structure", asking, "Where are the different sugar chain structures located? Are they part of CEA?" The Examiner indicates that the rejection could be overcome by indicating that the proteins selectively bind to a sugar chain structure on CEA.

Reconsideration of the rejection is respectfully requested in view of the proposed amendments to the claims. In the proposed amendments to claims 31-33, the phrase "on a carcinoembryonic antigen" has been added after "sugar chain structure."

**Claims 31-44 are rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.**

1) The Examiner states that there is no support for the additions to separate "first portion", "second portion", etc.

Reconsideration of the rejection is respectfully requested in view of the proposed amendments to the claims.

The intention of this recitation of the claims was not to limit the method to **separate** "first portions", "second portions", etc., but simply to distinguish the separate addition steps. For clarity, Applicants therefore amend "first portion", "second portion", etc., to -- portion --. As amended, the

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claims therefore do not specifically recite separate portions.

2) The Examiner states that the claims do not find support for the specific types of antibodies that may be used. The Examiner refers to claim 38 (although this appears to be a reference to claim 39, possibly considered as renumbered to claim 38).

Reconsideration of the rejection is respectfully requested in view of the amendment to claim 39. The Examiner is correct that this is a mistake in claim 39, which should have indicated undetectable Anti-Le<sup>a</sup> and detectable Anti-S-Le<sup>y</sup>. In claim 39, in the second to the last clause, "a detectable" is amended to – an undetectable –, and in the last clause, "an undetectable" is amended to – a detectable –. The amended recitation can be seen to be supported by Table 1 of the present specification on page 27, in which for colon cancer (second line of the table), there is an undetectable amount with Anti-Le<sup>a</sup> antibody, and a 2.0% ratio with Anti-Le<sup>y</sup> antibody.

3) The Examiner indicates that "the claims also do not have support for merely detecting cancer by using a certain quantity of proteins that bind to certain sugar chain structures." The Examiner refers to claims 31 and 32, and then states: "However, the ability to detect a particular type of cancer from a sample is much more quantitative. It is based on the ratio of the amount of the CEAs having a specific sugar chain relative to the total amount of CEAs in the sample ..."

Reconsideration of the rejection is respectfully requested.

In traversing this rejection, Applicants note first of all that the Examiner is somewhat mischaracterizing the claims when he refers to "the ratio of the amount of CEAs ..." The term "ratio" and the value of this ratio are not recited in the claims; the claims recite detection or non-detection of complexes corresponding to the different CEAs.

Moreover, Applicants submit that the Examiner's argument that:

"Furthermore, in some instances, only ONE antibody need be detected ... yet some of the claims (Claims 38, 40, 43) to specific cancers all ultimately depend from claim 31 which requires that two different sugar chain antibodies be added to first and second portions."

is unclear. Specifically, it is unclear what is meant by "need" in the statement that "only ONE antibody **need** be detected", and it is not stated why "need" is relevant here.

Applicants respectfully assert that the Examiner's argument with regard to "only ONE antibody" appears to be irrelevant, since, as the Examiner has noted, claim 31 clearly recites use of the first and second selective binding proteins (i.e., two antibodies), and this is a limitation of all of the claims. The issue is whether there is written support for this limitation, and the Examiner has not stated how the claims fail to meet the written disclosure requirement in this regard.

In fact, the specification clearly states, on page 7, line 14: "These specific sugar chain binding proteins may be used singly or in proper **combination of two or more thereof**" (emphasis added).

The present invention of claim 31 is a method for detecting cancer by reacting a sample (CEAs), two or more kinds of proteins (antibodies) capable of recognizing a modified sugar chain structure on CEAs and an antibody against a constant region of CEAs, and detecting whether some

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type of complex is formed. Claim 32 requires three kinds of proteins, and claims 33-35 and 37-44 require four kinds of proteins.

The Examples in Table 1 of the specification fully support the use of four antibodies to distinguish different cancers. It is also clear from the data in Table 1 that some of the cancers cannot be distinguished using only two or three antibodies.

Applicants therefore submit that there is full written disclosure for the recitations of the pending claims.

**Claims 31-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification ... does not reasonably provide enablement for the method as broadly claimed.**

The Examiner's argument appears to be that "one cannot extrapolate the teachings of the specification to the scope of the claims ..." (bottom of page 6 of the Office action) and "applicant has not enabled all of these types of proteins because it has not been shown that these proteins are capable of functioning as that which is being disclosed" (page 7, line 4, of the Office action).

The Examiner then states that "the specification lacks the necessary guidance for one of skill in the art to predictably detect cancer because it appears that the method is limited to a particular combination of anti-sugar antibodies, not just any lectin or protein."

The rejection of claims 31-35 is respectfully traversed and reconsideration of the rejection is respectfully requested.

In traversing the rejection, Applicants submit that the Examiner's remarks are not a valid argument against enablement of claims 31-35.

First of all, the present invention is already enabled by the working examples in the

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specification.

Secondly, while it is true, as the Examiner implies, that **some** lectins or anti-sugar chain antibodies might not be bind to any CEAs, this **does not affect the ability of one of skill in the art to carry out the method** as claimed; the method as claimed involves only adding these proteins, detecting the product, and determining a diagnosis based on this detection.

Thirdly, the selection of appropriate lectins and anti-sugar chain antibodies (other than those listed in the specification) for medically useful detection methods can be made **without undue experimentation**. For example, lectin or antibody selection can be made rationally from known information on types of CEAs present in cancer, which would require almost no experimentation. Alternatively, the testing of different lectins against known cancer samples to determine which would be useful would be straightforward and would not represent "undue experimentation".

Applicants submit that the Examiner's argument about testing "tens of thousands of lectins and proteins" in this regard is inappropriate. There is no requirement that the Applicants provide test data in the specification on every conceivable permutation of a claim. Testing of some different lectins or antibodies would clearly not be "undue experimentation", and one of skill in the art could clearly obtain additional working examples of the present claims with a modest amount of testing (certainly not tens of thousands of lectins and protein) that could not be considered "undue experimentation".

Again, reconsideration of the rejection is respectfully requested.


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If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact Applicants undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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